IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
(Northern Division)

UNITED STATES OF AMERICA v. RON ELFENBEIN, *Defendant.*	Crim. No. JKB-22-0146

DEFENDANT RON ELFENBEIN'S MOTION FOR JUDGMENT OF ACQUITTAL OR, IN THE ALTERNATIVE, FOR A NEW TRIAL

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INTRODUCTION

On August 4, 2023, a jury convicted Dr. Ron Elfenbein on all five counts of the Superseding Indictment charging him with health care fraud in violation of 18 U.S.C. § 1347.[1] The jury reasonably could have found that the regulatory scheme governing healthcare reimbursement in this country is complicated and absurd. The jury also reasonably could have found that Dr. Elfenbein's urgent care centers were not well-run during 2020 and 2021 when the country was in the midst of a pandemic. But these were not the questions before the jury. Instead, the jury was tasked with determining whether Dr. Elfenbein devised and executed a scheme to submit claims for reimbursement using Current Procedural Terminology ("CPT") codes that were incorrect, and that he knew were incorrect. As to these questions, the evidence was simply insufficient to convict.

The jury's verdict was not supported by the evidence, taken in the light most favorable to the government, and allowing it to stand would be an injustice and contrary to law. Pursuant to Federal Rule of Criminal Procedure 29, the Court should enter a judgment of acquittal on all counts. In the alternative, the Court should order a new trial pursuant to Federal Rule of Criminal Procedure 33.

BACKGROUND

In 2016, Dr. Elfenbein opened an urgent care center in Gambrills, Maryland, Drs ERgent Care ("DEC"), that provided "standard urgent care type services" such as "in-house laboratory, x-ray, minor in-office procedures, and office visits." *See* 8/1/23 Tr. 119:9–22; 7/20/23 Tr. 81:6–10. Shortly before the onset of the COVID-19 pandemic, DEC merged with a larger urgent care

[1] Due to a non-substantive error in the Superseding Indictment, the government filed an Amended Superseding Indictment. (ECF No. 51). In this motion, we refer to the operative indictment simply as the Superseding Indictment.

company, Centennial Medical Group, which had locations in Howard County, Maryland. *See* 8/1/23 Tr. 126:25–129:2; 7/20/23 Tr. 81:14–20; 7/24/23 Tr. 161:6–7. Dr. Elfenbein was Medical Director of the resulting entity operating in Gambrills, First Call Medical Center ("FCMC").[2] *See* 7/24/23 Tr. 161:3–18.

In March 2020, "due to COVID, there was a near overnight demand for COVID testing" and the volume of patients coming to DEC increased significantly. 7/20/23 Tr. 82:9–23. From mid-March 2020 through the end of February 2022, the period covered by the alleged scheme, DEC submitted thousands of claims for reimbursement to Medicare and other insurance companies. These claims included evaluation and management ("E/M") codes for office or other outpatient visits in addition to reimbursement for COVID-19 tests. *Id.* at 80:11–13. Dr. Elfenbein told DEC providers these office visits should be coded at levels 4 and 5 under the CPT Manual coding rubric, and most were coded at level 4. GX 140.

The allegations in the Superseding Indictment, and the facts developed at trial, are inextricably bound to the complex regulatory scheme that governed this CPT coding scheme for Medicare and CareFirst Blue Cross Blue Shield in 2020 and 2021.[3] Entering 2020, the CPT codes and their definitions, as well as guidance concerning their application, were found in the 2020 CPT

[2] Some witnesses at trial referred to Dr. Elfenbein's urgent care company as Drs ERgent Care and others referred to it as First Call. During the relevant period, claims were submitted under the DEC name, *see* 7/20/23 Tr. 82:4–8, but the company did business as FCMC, *see, e.g.*, 7/24/23 Tr. 13:23–14:4, 188:9–11. In this motion, we refer to the entity as DEC.

[3] The Superseding Indictment alleged a scheme involving claims submitted to other insurers as well. However, the government presented no evidence regarding the CPT coding standards of these other insurers. The Court thus effectively granted a judgment of acquittal with respect to the allegations that Dr. Elfenbein defrauded any insurers other than CareFirst and Medicare. *See* 7/26/23 Tr. 67:25–68:25 (prohibiting the government from presenting the jury with summary exhibits that treated as fraudulent claims submitted to insurers other than Medicare and CareFirst).

Manual. DX 3;[4] *see also* 7/18/23 Tr. 92:9–19. The correct code for a particular service, however, could not be determined from the Manual alone. For example, CPT code 99204 was defined as an "[o]ffice or other outpatient visit for the evaluation and management of a new patient, which requires these 3 components: A comprehensive history; A comprehensive examination; Medical decision making of moderate complexity." DX 3, p. 13. The terms "moderate" and "comprehensive" were not defined, and as confirmed by the government's own expert witness, Stephen Quindoza, the CPT Manual alone was not enough to determine what level of complexity to assign to an office visit:

> Q. . . . [D]etermining the complexity of medical decision making, **that's not just something that a coder or a provider determines based on the words**, what is low complexity, correct?
>
> A. Correct.
>
> Q. There is some guidance that's in the code book, right?
>
> A. Yes.
>
> Q. And then there's guidance in the 1995 documentation guidelines, correct?
>
> A. Yes.
>
> Q. And there's guidance in the 1997 documentation guidelines, correct?
>
> A. Yes, sir.

7/18/23 Tr. 191:10–22 (emphasis added); *see also id.* at 65:14–16; *id*. at 165:13–16. In this vein, Mr. Quindoza acknowledged that "[t]here's a lot" of additional guidance for providers regarding coding, 7/18/23 Tr. 153:16–18, and that there were "gaps" in the CPT Manual, *id*. at 161:5–9, 20–24. He further agreed that guidance designed to fill these gaps was, at times, inconsistent. *Id*.[5]

[4] Excerpts of the 2020 and 2021 CPT Manuals are in evidence as GX 902 and 903, and DX 3 and 4. We cite to the Defendant's exhibits because the pages of the exhibits are numbered.

[5] DEC's in-house coder and biller, Cathy Raymond, also acknowledged that the providers had to contend not only with the CPT Manual to determine an appropriate code, but also with "the audit

With the arrival of the COVID-19 pandemic, the government promulgated additional regulations regarding CPT code selection that addressed the extraordinary needs caused by this novel, unprecedented public health emergency. A Department of Health and Human Services Centers for Medicare & Medicaid ("CMS") Interim Final Rule published on April 6, 2020 and effective retroactively to March 1, 2020 explicitly encouraged the use of telehealth to minimize the spread of disease:

> In support of the imperative to contain and combat the virus in the United States, this [interim final rule] will give health care workers and hospitals *additional flexibility* to respond to the virus and continue caring for patients while minimizing exposure. CDC guidelines are clear that public exposure greatly increases the overall risk to public health and they stress the importance of containment and mitigation strategies to minimize public exposure and the spread of COVID–19.
>
> [. . .]
>
> The provisions of this [interim final rule] better enable and facilitate physicians and other clinicians, to focus on caring for these beneficiaries during this [public health emergency] for the COVID–19 pandemic and minimize their own risks to COVID–19 exposure. For example, *by increasing access to telehealth* and testing in a patient's home, and improving infection control, this [interim final rule] will provide flexibilities for Medicare beneficiaries to be able to receive medically necessary services without jeopardizing their health or the health of those who are providing those services, in turn minimizing public exposure and the overall risk to public health. Moreover, *changes to Medicare payment rules will confer on practitioners and other healthcare providers the broadest flexibility to use remote communications technology* to avoid exposure risks to themselves, their patients, and communities.

DX 218, p. 53 (emphasis added).

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tools that Novitas [the Medicare Administrative Contractor for the region] had put out." 7/24/23 Tr. 37:18–38:23.

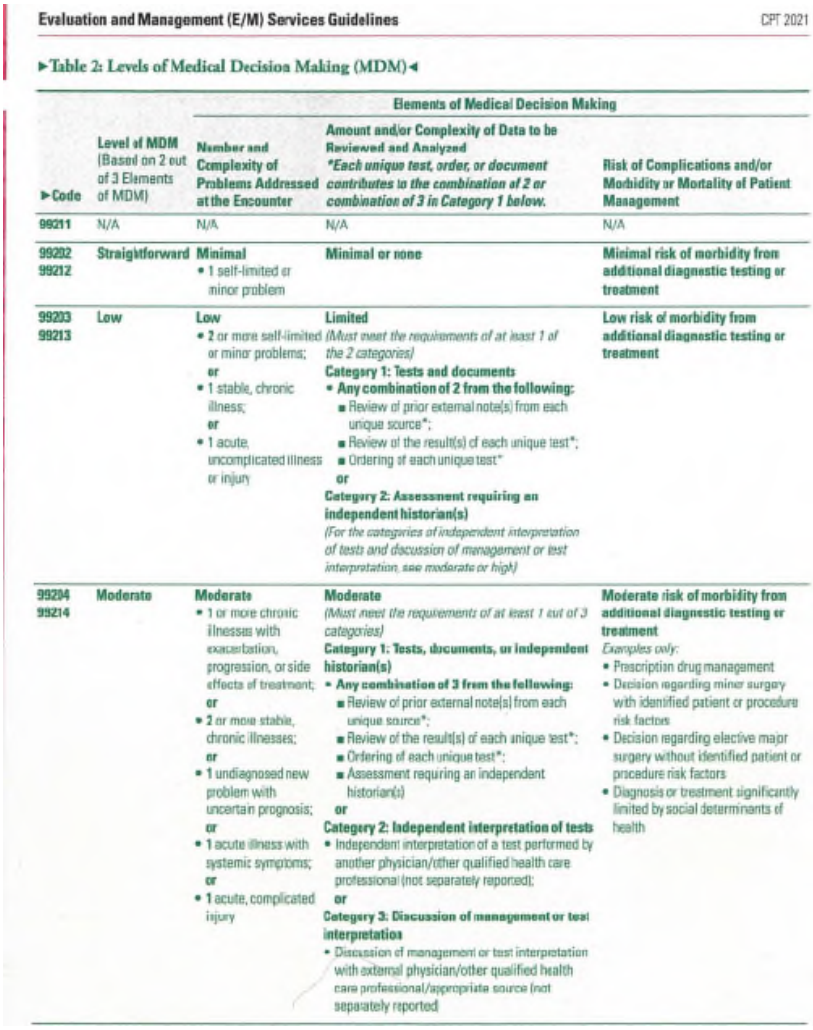
Significantly, CMS recognized that examinations via telehealth are more limited than what can be accomplished during in-person visits. To encourage use of telehealth for COVID-related visits, CMS "revis[ed] [its] policy to specify that the office/outpatient E/M level selection for these services when furnished via telehealth [could] be based on MDM or time," and "remov[ed] any requirements regarding documentation of history and/or physical exam in the medical record." *Id*., p. 41. In other words, even if a provider elected to perform a history and/or physical exam, the provider had no obligation to document those aspects of the visit in the patient's chart. The April 2020 Interim Final Rule, then, operated as a retroactive telehealth exception that removed the history and exam requirements in the 2020 CPT Manual.

In 2021 (the year of service for the patients identified in each of the five counts of the Superseding Indictment), the CPT E/M coding guidelines underwent a significant change. For all office visits, code selection was no longer based on a "three key factors model" (history, exam, and medical decision making). *See* 7/24/23 Tr. 37:18–38:23; *see also* DX 3. Instead, providers were to code visits based on "medical decision making (MDM) ***or*** time," DX 4, p. 5 (emphasis in original), as they had been doing for telehealth visits throughout the pandemic. The extent of the history and examination were eliminated as factors in code selection even for in-person visits, and, in fact, a history and examination were not required at all. "Office or other outpatient services included a medically appropriate history *and/or* physical examination, *when performed*. . . . The extent of history and physical examination is *not an element in selection of the level* of office or other outpatient codes." *Id*., p. 12 (emphasis added).

Under the new 2021 CPT guidelines, an office visit assigned CPT code 99204—and coded based on medical decision making rather than time[6]—was one in which the provider employed

[6] It is undisputed that the claims at issue in this case were not coded based on time.

"moderate complexity" medical decision making. *Id.*, p. 19. "Moderate complexity" medical decision making was not "just something that a coder or a provider determine[d] based on the words." *See* 7/18/23 Tr. 191:10–22. The CPT Manual included a medical decision making chart, which broke down the levels of complexity into their component parts and quantified the requirements for each level of medical decision making:



Evaluation and Management (E/M) Services Guidelines CPT 2021

▶Table 2: Levels of Medical Decision Making (MDM)◀

		Elements of Medical Decision Making		
▶Code	Level of MDM (Based on 2 out of 3 Elements of MDM)	Number and Complexity of Problems Addressed at the Encounter	Amount and/or Complexity of Data to be Reviewed and Analyzed **Each unique test, order, or document contributes to the combination of 2 or combination of 3 in Category 1 below.*	Risk of Complications and/or Morbidity or Mortality of Patient Management
99211	N/A	N/A	N/A	N/A
99202 99212	Straightforward	**Minimal** • 1 self-limited or minor problem	**Minimal or none**	**Minimal risk of morbidity from additional diagnostic testing or treatment**
99203 99213	Low	**Low** • **2** or more self-limited or minor problems; **or** • 1 stable, chronic illness; **or** • 1 acute, uncomplicated illness or injury	**Limited** *(Must meet the requirements of at least 1 of the 2 categories)* **Category 1: Tests and documents** • **Any combination of 2 from the following:** ▪ Review of prior external note(s) from each unique source*; ▪ Review of the result(s) of each unique test*; ▪ Ordering of each unique test* **or** **Category 2: Assessment requiring an independent historian(s)** *(For the categories of independent interpretation of tests and discussion of management or test interpretation, see moderate or high)*	**Low risk of morbidity from additional diagnostic testing or treatment**
99204 99214	Moderate	**Moderate** • 1 or more chronic illnesses with exacerbation, progression, or side effects of treatment; **or** • **2** or more stable, chronic illnesses; **or** • 1 undiagnosed new problem with uncertain prognosis; **or** • 1 acute illness with systemic symptoms; **or** • 1 acute, complicated injury	**Moderate** *(Must meet the requirements of at least 1 out of 3 categories)* **Category 1: Tests, documents, or independent historian(s)** • **Any combination of 3 from the following:** ▪ Review of prior external note(s) from each unique source*; ▪ Review of the result(s) of each unique test*; ▪ Ordering of each unique test*; ▪ Assessment requiring an independent historian(s) **or** **Category 2: Independent interpretation of tests** • Independent interpretation of a test performed by another physician/other qualified health care professional (not separately reported) **or** **Category 3: Discussion of management or test interpretation** • Discussion of management or test interpretation with external physician/other qualified health care professional/appropriate source (not separately reported	**Moderate risk of morbidity from additional diagnostic testing or treatment** *Examples only:* • Prescription drug management • Decision regarding minor surgery with identified patient or procedure risk factors • Decision regarding elective major surgery without identified patient or procedure risk factors • Diagnosis or treatment significantly limited by social determinants of health

DX 4, p. 16; *see also id.*, p. 17 (breakdown of complexity required for CPT codes 99205 and 99215).

At trial, the government established several undisputed facts: (1) when patients presented to DEC seeking a COVID-19 test, they received a rapid test, a PCR test, and an office visit with a

healthcare provider;[7] (2) the office visits typically involved roughly five minutes of face-to-face time with a provider, whether in person or via telehealth; (3) Dr. Elfenbein instructed providers, as a general matter, to bill these office visits at CPT level 4 if the patient was asymptomatic or level 5 if the patients was symptomatic; and (4) the vast majority of DEC office visits in 2020 and 2021 were billed at level 4. What the government did *not* establish was that the E/M Level 4 and 5 code selections were incorrect under the applicable CPT Manual codes and guidance. The central allegation in the Superseding Indictment was that the office visits did not meet the requirements for these codes, and, accordingly, the claims for level 4 office visits on the same day as COVID tests were false statements. Thus, absent evidence from which a jury could find beyond a reasonable doubt that the codes were incorrect, there was no false or fraudulent statement to support the alleged scheme to defraud.

ARGUMENT

I. THE COURT SHOULD GRANT THE MOTION AND ENTER A JUDGMENT OF ACQUITTAL UNDER RULE 29.

Under Rule 29(a), "the court on the defendant's motion must enter a judgment of acquittal for any offense for which the evidence is insufficient to sustain a conviction." The "critical inquiry" in determining whether a Rule 29 motion should be granted "is whether the record evidence could reasonably support a finding of guilt beyond a reasonable doubt." *Jackson v. Virginia*, 443 U.S. 307, 318 (1979). "[I]f the evidence is so insufficient that *no* rational trier of fact could convict, the court should enter a judgment of acquittal." *United States v. Rafiekian*, 68 F.4th 177, 186 (4th Cir.

[7] Patients sometimes received additional tests if the provider believed them necessary. *See, e.g.*, 7/26/23 Tr. 23:12–18, 57:3–8 (testimony of Kathleen Wrona). On infrequent occasions, patients only received a rapid test. *See* 8/1/23 Tr. 183:4–14 (testimony of Dr. Elfenbein); 8/2/23 Tr. 169:11–173:13 (testimony of Dr. Elfenbein); GX 938. The patients whose visits constituted counts in the indictment, like most patients, received rapid and PCR tests.

2023). In making this determination, "the court views the evidence and inferences therefrom in the light most favorable to the government." *Id*. (internal quotation marks omitted). Under this standard, there was insufficient evidence for the jury to convict Dr. Elfenbein.

A. The evidence was insufficient to establish that CPT codes 99204 and 99214 inaccurately represented E/M services provided to patients seeking COVID-19 testing services.

Health care fraud requires proof of the knowing and willful use of "false or fraudulent pretenses, representations, or promises" to obtain the money or property of a health care benefit program. *United States v. Jones*, 471 F.3d 478, 481(3d Cir. 2006); *see also, e.g.*, *United States v. Memar*, 906 F.3d 652, 656 (7th Cir. 2018); *United States v. Medina*, 485 F.3d 1291, 1298 (11th Cir. 2007). The Superseding Indictment alleged a "scheme" in which Dr. Elfenbein "instructed providers and other employees" to bill office visits occurring alongside COVID-19 tests "as moderate complexity E/M Services" ("represented" by CPT codes 99204 and 99214) "even though such encounters did not occur as represented." Sup. Ind. ¶¶ 30(e), (f) (ECF No. 51). The *sine qua non* of the alleged scheme was thus that the codes did not describe the services. *Id*. ¶ 29(a), 30(c)–(d), (h); *see* Jury Instruction No. 39 (ECF No. 64). Evidence from which the jury could find that the codes were wrong was therefore essential; without it, the jury could not convict. [8]

[8] Throughout the trial, the government suggested that *no* provider visit was medically necessary for patients presenting to FCMC for COVID-19 testing. *See, e.g.*, 7/18/23 Tr. 21:9–13 (government opening); 7/25/23 Tr. 20:6–10 (questioning patient whether she wanted a test, or to see a doctor); 8/1/23 Tr. 47:17–48:13 (questions pertaining to CPT code 99211); 8/3/23 Tr. 89:12–90:9 (government closing). The government, however, presented no evidence to support this theory. The only testimony regarding medical necessity was offered through the defense's expert witness, Dr. Hugh Hill. Dr. Hill's unrefuted expert opinion was that patients presenting for COVID-19 testing should be seen by a healthcare provider. 7/31/23 Tr. 74:25–75:24 ("Physicians don't just dole out tests, nor nurse practitioners, nor providers. It's just not what we do. We're not dispensers or access points for tests."). Moreover, CMS and the CDC urged providers to meet with patients—including asymptomatic patients—at the time they were tested, in the interest of the health of both patients and the public. DX 233, p. 3 (7/30/2020 CMS and CDC joint press release). CMS also announced that it would "use existing evaluation and management (E/M) payment codes to

The government, however, offered insufficient evidence to support the allegation that codes 99204 and 99214 were, in fact, the wrong codes. The government offered no expert testimony concerning the applicability of level 4 E/M codes to patient encounters at any of the DEC locations. Instead, the government relied on the opinions of numerous fact witnesses, many of whom disagreed on what the rules meant and what the codes should have been. The insufficient evidence that the codes were wrong was fatal to the government's case.[9]

i. No expert testimony established that level 4 was incorrect.

"Expert testimony is required when the subject matter is so particularly related to some science or profession that it is beyond the ken of the average layman." *Adams v. NVR Homes, Inc.*, 142 F. Supp. 2d 649, 654 (D. Md. 2001). The government's case against Dr. Elfenbein hinged on whether CPT codes 99204 and 99214 accurately described the services provided to patients at DEC. "The ordinary juror is not expected to have knowledge regarding CPT codes." *Counts v. Pollock*, No. 3:18-CV-1072-J-39JBT, 2020 WL 5534444, at *3 (M.D. Fla. Aug. 21, 2020); *see also United States v. Diaz*, No. 07-20398-CR, 2008 WL 906725, at *6 (S.D. Fla. Mar. 28, 2008) ("Medicare billing codes . . . [are] beyond the knowledge of an ordinary juror."). Given the complex regulatory backdrop of this case, the government was required to provide the jury with

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reimburse providers" for these office visits. *Id*. Indeed, CMS reinstated the requirement of a provider's order for all COVID tests except a patient's first one to ensure that providers would receive "the medical attention and oversight required to ensure that diagnosis and treatment is applied consistent with CDC guidelines and other medical standards," and instructed that these services be billed using E/M codes "to ensure that physicians and other practitioners . . . are paid for these services." DX 220, p. 20 (9/2/20 Interim Final Rule). CMS's interim final rule thus established that an E/M visit at the time an asymptomatic patient was tested was *always* medically necessary.

[9] In this regard, if the evidence is insufficient to establish that the codes that were utilized were wrong, it is of no moment whether DEC employees told Dr. Elfenbein that they were uncomfortable with using these codes, or that he selected these codes in order to maximize reimbursement, which addresses the separate question of Dr. Elfenbein's motive and knowledge.

an expert opinion based upon which jurors could conclude that level 4 was not the correct code. The government did not do so. Instead, the government argued that the applicability of CPT codes was a matter of common sense, and then argued that the jury should adopt government counsel's own contention that the applicable code was level 1—unsupported by any expert or other testimony. *See* 8/3/23 Tr. 89:12–90:9, 94:6–17. Without expert testimony that the level 4 CPT codes selected for most patient encounters did not describe the services rendered, and therefore were false representations, the government could not establish that the codes were wrong.

In order to meet its burden, the government presented the testimony of only one expert, Stephen Quindoza, who was qualified as an expert in "Medicare processes, rules, and regulations," and "procedural and diagnostic coding." 7/18/23 Tr. 62:16–21. Mr. Quindoza did not offer "any opinions concerning the medical necessity of a particular patient's E/M visit," 7/18/23 Tr. 126:12–15. He offered no opinions "concerning the care of any patient or all patients received" at DEC. *Id*. at 126:16–18. He offered no testimony concerning the correct CPT code for any office visit during the two-year period of the alleged scheme. Instead, Mr. Quindoza's testimony was intended to establish the general rules governing CPT code selection. But even in this narrowly defined scope, Mr. Quindoza failed to offer any testimony that supported the government's theory. Indeed, as the Court noted, rather than bolstering the government's case, Mr. Quindoza's testimony undermined "the underlying sort of legal foundation for it all." 7/19/23 Tr. 29:11–12.

While Mr. Quindoza's testimony did not remotely assist the jury in determining whether the correct codes were used for patients seen at DEC, including the five named patients in the Superseding Indictment, his testimony regarding the substantive requirements for E/M code selection did overwhelmingly illustrate both the complicated and confusing regulatory environment and his lack of knowledge of the controlling rules. For example, he initially testified

that time was a relevant factor in determining the appropriate CPT code for E/M office visits in both 2020 and 2021. 7/18/23 Tr. 95:18–21, 100:15–18. On cross-examination, however, Mr. Quindoza retracted that testimony:

> Q. Okay. So when you told the members of the jury earlier that time is a factor in determining the level, that's just not true, is it?
>
> A. In determining the level?
>
> Q. Yes, sir.
>
> A. No, it's not.
>
> [. . .]
>
> Q. . . . [I]t's not a factor that a provider can rely on in selecting the level, correct? Assuming no counseling or coordination of care.
>
> A. Understand. Yes.

7/18/23 Tr. 205:6–25.[10]

On another issue of critical importance to this case—the role of the COVID-19 pandemic in E/M code selection—Mr. Quindoza's testimony was similarly contradictory. He initially testified that the expansion of telemedicine during the COVID-19 pandemic had no impact on the requirements for CPT code selection:

> Q. . . . Did the requirements for telemedicine change with the COVID pandemic?
>
> A. Yes, sir, it did.
>
> [. . .]
>
> Q. And did these changes reduce any of the requirements for the evaluation and management CPT codes?

[10] Indeed, Mr. Quindoza's testimony concerning the relevance of time in determining the level had been based on the "typical" times in the code descriptions (which were established before the pandemic). But in 2021—when all the substantive counts occurred—the CPT Manual eliminated "typical" times for E/M office visit codes. DX 4, pp. 18–20. For all visits—not just telehealth—providers were permitted to select a code based on medical decision making or time, at the provider's choice, and each code definition included a range that applied only "when using time for code selection." *Id.* If the provider chose to code based on medical decision making, time was simply irrelevant.

> A. No, sir.
>
> Q. Did the changes reduce any of the things that a provider needed to do to meet the requirements of those codes?
>
> A. No.

7/18/23 Tr. 105:12–106:20. But he acknowledged on cross-examination that he had not read CMS's April 6, 2020 Interim Final Rule, or any of the other Interim Final Rules that CMS published in the federal register during the pandemic, or even the transmittals from CMS to its contractors. 7/19/23 Tr. 22:13–22, 32:11-33:20. He was, therefore, unaware that in the April 2020 Interim Final Rule, CMS "remove[d] any requirements regarding documentation of history and/or physical exam in the medical record." *See* 7/19/23 Tr. 15:3–6; DX 218, pp. 41, 53. Mr. Quindoza admitted his mistake on the stand:

> Q. . . . So the provisions in this interim final rule were effective going back to March 1st of 2020, although they were published in the Federal Register on April 6th, correct?
>
> A. Yes, sir.
>
> Q. All right. And that includes the provision that said, for telemedicine, the rule that applied -- that was going to apply in 2021 to all visits, which is that the level is determined based on time or medical decision making, the option of the provider, for telemedicine that was effective as of March 1st of 2020. Is that true?
>
> A. Yes, sir.
>
> Q. Okay. All right. So your testimony on direct examination that there were no changes to level selection or to the rules that relate to the E/M codes in the requirements in 2020 was incorrect? Is that --
>
> A. You are correct.
>
> Q. I'm sorry?
>
> A. You are correct.

7/19/23 Tr. 18:8–25.

Taken as a whole, Mr. Quindoza's testimony established that the length of an office visit did not affect the selection of the code for telemedicine and in-person office visits, and that CMS

eliminated the requirements of documentation of an examination and history for telemedicine during the pandemic. More significantly, his testimony clearly established that even an expert whose "job [it is] to know these sorts of changes," *see* 7/19/23 Tr. 20:22–25, was unaware of the changing guidance. Mr. Quindoza's testimony certainly provided no basis on which the jury could reasonably conclude that CPT codes 99204 and 99214 were inappropriately applied to the visits at issue in this case. In this regard, the government's reliance on time as well as examination and history to establish the allegations in the Superseding Indictment was both incorrect and misleading.

The only other expert who testified regarding CPT coding was the defense witness, Michael Miscoe. Mr. Miscoe was qualified as an expert in medical coding, E/M coding, diagnostic coding, and documentation of medical services in medical records. 7/31/23 Tr. 132:6–133:4. Consistent with other government witnesses, Mr. Miscoe testified that the 2020 CPT Manual included numerous undefined terms, the meaning of which could not be determined from review of the Manual itself. *Id*. at 143:8–149:13. Mr. Miscoe's uncontradicted expert opinion was that, under the applicable coding guidance, COVID was an "undiagnosed new problem with an uncertain prognosis," a term with relevance in determining the complexity of medical decision making that occurred during an office visit and the resulting E/M level. 7/31/23 Tr. 173:11–174:6; DX 4, p. 16 (MDM Table).[11]

[11] Mr. Miscoe testified that CMS's guidance regarding the use of COVID diagnostic codes instructed providers and coders not to use the new COVID screening code during the pandemic, but instead, to assign to all COVID tests for which there was not a confirmed COVID diagnosis—even encounters for preoperative testing, traveling, or to return to school—the code for "actual or suspected exposure to COVID-19." *Id.* at 173:11–174:6; DX 221, p. 7. The guidance instructed that, "given the Public Health Emergency, . . . everybody was suspected to have COVID until it was proven that they did not." 7/31/23 Tr. 174:22–175:6. The government ignored this binding guidance in repeatedly arguing during trial that the fact that patients came to DEC "simply" to be tested for work or travel was evidence of a fraudulent scheme. *See* pp. 26–27 *infra.*

Moreover, unlike Mr. Quindoza, Mr. Miscoe offered expert testimony regarding the coding of specific office visits that occurred at DEC: the five visits that were the subject of indictment counts and a number of other visits that were part of the CareFirst audit. Mr. Miscoe's uncontradicted expert opinion was that the charts he reviewed supported the level 4 codes. 7/31/23 Tr. 200:18–25; 8/1/23 Tr. 3:19–7:18, 14:5–15.[12]

The jury was not required to credit Mr. Miscoe's testimony simply because he was an expert. But this case involved technical rules that experts spend years learning and applying, and that rapidly changed during the pandemic. The government cannot supplant the testimony of an expert concerning such rules by making up different rules out of whole cloth. Yet that is what the government did. Government counsel's own personal views as to whether E/M level 4 was the appropriate code for these encounters cannot replace the uncontradicted testimony of the defendant's expert. Accordingly, the Court should grant the defendant's motion and enter judgment in his favor.

ii. None of the government's fact witnesses provided a basis for the jury's determination that level 4 was incorrect.

Assuming that the jury could ignore the only expert who testified as to the proper method of coding the visits at issue, the testimony of the government's fact witnesses similarly failed to establish a basis for the jury to find that 99204 and 99214 were the wrong codes. For example, Cathy Raymond, DEC's former biller and coder, acknowledged the "rapidly changing regulatory environment" as she "considered multiple different code options to see which one actually

[12] Mr. Miscoe's testimony that patients who were tested each had an undiagnosed problem with uncertain prognosis, which formed the basis for his conclusion that Level 4 was the appropriate E/M code, was supported by the E/M worksheet created by Novitas, the Medicare Administrative Contractor for Maryland.

accurately described the service and which one would be compliant. 7/20/23 Tr. 97:1–5. And although Ms. Raymond testified that she raised concerns to Dr. Elfenbein that "the *documentation level* that was there did not justify the high level office visits," *see* 7/20/23 Tr. 84:18–19 (emphasis added), she agreed that she was "okay" with billing COVID-related visits at level 4 and 5 "[i]f I had the documentation to support it in the history and the exam." 7/24/23 Tr. 45:16–18; *see also* GX 602. Based on the level of documentation, she believed "the majority of patient encounters that were billed" in 2020 should have been a level 3. *See* 7/24/23 Tr. 49:10–19. Significantly, at no point did Ms. Raymond testify that the visits at issue *did not involve* moderate levels medical decision making. Her disagreement with what she perceived as a "pattern of over coding" had everything to do with documentation of the history and exam, and nothing to do with medical decision making. *See, e.g.*, 7/24/23 Tr. 48:17–49:4, 90:7–14. This critical point undermines her testimony on code selection entirely.

Moreover, Ms. Raymond left DEC in 2020 and offered no testimony regarding its coding practices in 2021, when all the patients named in the Superseding Indictment were seen. *See* 7/24/23 Tr. 42:19–21. Based on that fact alone, Ms. Raymond's testimony provided no basis on which the jury could reasonably conclude that CPT codes 99204 and 99214 were incorrect.

The government's provider witnesses, Deborah Needle and Kathleen Wrona, offered even less relevant testimony on this critical issue. Ms. Needle, who worked at DEC from 2019 to 2020, testified that she had no coding experience and was "[n]ot really" familiar with E/M codes. 7/24/23 Tr. 134:2–7. She nevertheless testified that she "didn't *feel* that an asymptomatic patient warranted a level 4," 7/24/23 Tr. 139:10–11 (emphasis added), a feeling not grounded in any rules or regulations, *see* 7/24/23 Tr. 142:17–19. Ms. Needle "felt" that level 3 was the "more appropriate level" for asymptomatic COVID patients, "but I had never lived through a pandemic before," and

thus "accepted" Dr. Elfenbein's instructions that level 4 was correct. *See id*. at 206:11–207:7. Ms. Wrona, who worked at DEC in 2021, also had no experience with CPT codes. 7/26/24 Tr. 35:22–23 ("I had never coded before"). She did not testify to any discomfort with coding at level 4.

Ms. Needle and Ms. Wrona did, however, testify about the types of medical decisions they made when treating patients who came to DEC for COVID tests. Ms. Needle testified that she made decisions about (1) whether a patient was symptomatic or asymptomatic; (2) whether a patient might need to go to the hospital; (3) whether a patient needed medication; and (4) what advice and recommendations to give to a patient. 7/24/23 Tr. 190:11–191:11. Ms. Wrona testified that she made decisions about (1) whether to refer patients for monoclonal antibody treatments; (2) whether a patient's vital signs indicated an issue such as "happy hypoxia"; and (3) whether tests other than COVID tests needed to be administered. 7/26/23 Tr. 17:25–19:12, 23:12–18. Ms. Needle and Ms. Wrona offered no testimony about where this level of medical decision making fell within the applicable CPT coding guidance.[13]

The only other government witness to testify about the E/M coding decisions at DEC was Courtney Sinagra, a representative of CareFirst Blue Cross Blue Shield. Ms. Sinagra testified regarding two CareFirst audits performed on a subset of DEC records, each of which had been performed by auditors who were no longer employed at CareFirst. Her fact testimony also failed to establish that CPT codes 99204 and 99214 were inappropriate as applied to office visits occurring alongside COVID tests at DEC. She testified that in 2021, CareFirst conducted an audit

[13] Every provider who testified—whether called by the government or the defense—described significant, meaningful encounters with patients. Code selection was not based on the examination or history in 2021, or in 2020 for telemedicine, but the providers' testimony described physical examinations when patients were seen in-person, and visual examinations when they were seen by telemedicine. *See, e.g.*, 7/24/2023 (Needle) Tr. 134:12–17 ("We were pulling blood pressure cuffs out the door. We were taking all our equipment out the back door. We were seeing patients in their car. We were climbing in the cars to see patients. It was -- it was -- it was chaos.").

of 30 patient records. 7/25/23 Tr. 30:1–24. Ms. Sinagra admitted that the first audit was based on review of medical records that were missing pages and were, in many cases, unintelligible due to fax transmission errors. *Id*. at 30:25–33:2. Based on these incomplete records, CareFirst determined that the charts—which were coded level 4—instead should have been coded level 3. *See* 7/25/23 Tr. 112:23–113:21; 130:9–131:3. Ms. Sinagra also testified that in 2021, CareFirst conducted a second audit of 89 patient charts. *Id*. at 34:18–21. This time, based on review of records from roughly the same time period, CareFirst concluded that the charts should have been coded at level 2. *Id*. at 54:23–56:7. When asked about this discrepancy in the audit findings, she agreed that "auditors don't necessarily make the same findings as to specific claims," and that "a one-level difference would not . . . necessarily be out of the ordinary." *Id*. at 149:23-150:3. Ms. Sinagra also agreed that, given the incomplete records on which the first audit was based, she did not know whether the complete records supported level 4. *Id*. at 127:21–128:11. Finally, Ms. Sinagra testified that COVID exposure could be considered "an undiagnosed problem of uncertain prognosis," a key factor in determining whether an office visit involved moderate levels of medical decision making. *Id*. at 171:21–23.

Because the government did not offer Ms. Sinagra as an expert, the jury had no basis on which to find that her testimony supported even the contradictory conclusions of CareFirst auditors regarding the audited claims—either that the claims in the first audit coded as level 4 should have been coded as level 3, or that the indistinguishable claims in the second audit should have been coded as level 2. On direct examination, the government did not ask her any questions concerning the reasons for CareFirst's audit findings, and on cross-examination, the government successfully objected to questions that would have tested her knowledge of the relevant regulatory changes and the broader applicability of CareFirst's audit findings because she was not testifying as an expert.

See 7/25/23 Tr. 77:16–78:18. Testimony of a witness insulated from cross-examination about "policies and procedures and codes and guidance" that governed code selection during the pandemic, *id.* at 78:10–13, who testified only to "what CareFirst did" in its audits, *id.* at 78:13–14, could not provide a basis for a jury finding concerning the codes applicable to claims that were not the subject of the CareFirst audit. Without such testimony, the jury could not reasonably find beyond a reasonable doubt that the government proved that the codes selected were wrong—and therefore could not find that the government proved the charged scheme to defraud.[14]

B. The jury had no reasonable basis to find that Counts 2–5 constituted executions of the alleged scheme because there was insufficient evidence that the CPT codes that were utilized were wrong.

Each of the five counts in the Superseding Indictment corresponds to a specific office visit for a patient that the government contends was improperly coded at level 4. Even if the Court were to find sufficient evidence to support a jury finding that there was a scheme to defraud, conviction on any of the counts required proof that the code submitted was wrong—*i.e.*, that the claim was false or fraudulent. 8/3/23 Tr. 127:9–14 (instructing jury, "You may not find the defendant guilty of a count in the Superseding Indictment unless you find the Government has proved beyond a reasonable doubt that the claim charged in that count of the Superseding Indictment was false or fraudulent as to a material fact or matter."). With respect to each count, the evidence was plainly insufficient to establish that level 4 was the wrong level for these visits.[15] Accordingly, no

[14] The defense also called two DEC providers to testify at trial. Both providers, Steven Carroll and Suzana Silva, testified that they billed their COVID-related visits at a level 4 because they believed level 4 accurately reflected the services they performed. *See* 7/31/23 Tr. 22:4–23:7; 8/1/23 Tr. 106:14–107:7. Ms. Silva was familiar with E/M coding and chose level 4 based on her own experience with and understanding of the codes, not based on Dr. Elfenbein's instructions.

[15] This section deals specifically with Counts 2–5. Count 1 will be addressed separately in the next section.

reasonable jury could have found beyond a reasonable doubt that the submissions of these level 4 claims constituted executions of the "scheme."

The visits corresponding to all five counts occurred in 2021. Sup. Ind. ¶ 31. Accordingly, E/M code selection was based *either* on the length of the visit *or* on the level of medical decision making. DX 4, p. 14 (2021 CPT Manual). No history or physical examination was required, but "when performed," the "history *and/or* physical examination" were to be "medically appropriate . . . as determined by the treating professional or other qualified health care professional reporting the service." *Id*., p. 12 (emphasis added). Further, all five counts also occurred via telehealth, so there were no "requirements regarding documentation of history and/or physician exam in the medical record." DX 218, p. 41.

Given this backdrop, the jury could have found that the visits were improperly coded at level 4 *only* if they determined that the rendering provider did not perform moderate complexity medical decision making. But the jury was not permitted to make its own assessment about what "moderate medical decision making" *should* mean—the jury was required to judge the visits according to the applicable rules. *See* 7/18/23 Tr. 191:10–22 (testimony of Quindoza) ("Q. . . . determining the complexity of medical decision making, that's not just something that a coder or a provider determines based on the words . . . correct? A. Correct."). Stated another way, in order to find that a false statement was made in the submission of the claim, the jury needed to find that each patient's provider *did not* consider the patient to have "1 undiagnosed new problem with uncertain prognosis"; or *did not* order two unique tests or review one of those tests. *See* DX 4, p. 16 (MDM Table). There simply was not enough evidence for the jury reasonably to make those findings with respect to the patient encounters that constituted these counts.

i. Count 5: S.T., date of service 4/19/21

S.T. testified that she and members of her family received multiple tests at the Earleigh Heights location of DEC. 7/24/23 Tr. 97:23–98:4. S.T. was herself tested on April 19, 2021 due to a COVID outbreak at her daughters' daycare. *Id*. at 99:1–5. At the time of S.T.'s visit, she had an unknown direct exposure to her COVID-positive daughter, which was revealed by her daughter's positive rapid test the same day. *Id*. at 120:7–25. S.T. received both a rapid test and a PCR test. *Id*. at 102:22–25. She testified that she saw a provider via telehealth and that the visit was brief. S.T. remembered a discussion about why she came to DEC and whether she had symptoms. *Id*. at 101:11–17. Notably, S.T. testified that she had trouble remembering the specifics of any particular encounter, given that she visited DEC multiple times. 7/24/23 Tr. 101:18–20.

According to S.T.'s medical record, the provider she saw on April 19, 2023 was named Alyssa Suchar. GX 408, p. 7. The government did not call Ms. Suchar to testify. Consequently, S.T.'s medical record from April 19, 2021—which Ms. Suchar completed and signed the same day—was the only evidence of the medical decision making that occurred during the visit. The record indicates (1) that S.T.'s presenting problem was possible COVID exposure; (2) that she received two COVID tests, one rapid and one PCR; and (3) that the results of S.T.'s rapid test were reviewed on the same day as her visit. GX 408, pp. 7–8. On these points, S.T.'s testimony and the medical record are consistent. Accordingly, based on the applicable coding guidance, S.T.'s exposure to COVID-19 meant that she had an undiagnosed problem with uncertain prognosis. Because she had two tests ordered and one result reviewed, her visit qualified as a level 4. Of course, the defendant has no burden to prove what code should have applied; the government was required to prove that it was *not* level 4. There was simply not enough evidence from which the jury could conclude beyond a reasonable doubt that level 4 was the wrong code for this visit.

ii. Count 4: J.J., date of service 3/2/21

J.J. testified that she received a COVID test at Earleigh Heights "on or about" March 2, 2021 because she had been exposed at work and because she had symptoms. 7/25/23 Tr. 3:15–17, 8:2–9:2, 16:8–13. She testified that someone swabbed her nose, *see id*. at 10:2–4, 14:13–15, that she saw a provider, and that the visit was short, *see id*. at 6:17–21, 9:24–10:4. J.J. testified that she could not remember how she received her COVID results. *Id*. at 7:1, 19:17–25. She also agreed that, due to the passage of time, "it's possible there were things that happened at that visit that [she didn't] specifically remember." *See id*. at 17:16–20.

According to J.J.'s medical record from March 2, 2021, she saw a provider named Nikita Shah. GX 405, p. 7. The government did not call Ms. Shah to testify. As a result, J.J.'s medical record from March 2, 2021—which Ms. Shah completed and signed that same day—was the only evidence of the medical decision making that occurred during the visit. The record indicates (1) that J.J.'s presenting problem was COVID exposure; (2) that she received two COVID tests, one rapid and one PCR; and (3) that the results of J.J.'s rapid test were reviewed on the same day as her visit. GX 405, pp. 7–8. J.J.'s limited recollection of her March 2, 2021 visit was not inconsistent on these points. Her contemporaneous triage form, completed in her writing, reflects that she had fatigue, nasal congestion, headaches, and sweats, and she suffered from asthma. GX 405, p. 10; *see also* 7/25/23 Tr. 16:25–17:5. Based on the applicable coding guidance, J.J.'s presentation (with symptoms) meant that she had an undiagnosed new problem with uncertain prognosis, and the two tests ordered and one reviewed established decision making of moderate complexity. There was simply not enough evidence for the jury to conclude beyond a reasonable doubt that level 4 was the wrong code for this visit.

iii. Count 3: D.M., date of service 5/10/21

D.M. testified that she received a COVID test at Earleigh Heights in May 2021. 7/20/23 Tr. 67:21–23. She testified that her nose was swabbed, that she saw a doctor on a screen, and that the visit "wasn't long." *Id*. at 68:1–5, 69:19–21. D.M. remembered that she received two tests, but little else. *Id*. at 69:11–18, 70:15–19. D.M. also initially testified that she needed a COVID test to visit her mother-in-law, *id*. at 69:8–10, but later acknowledged that she completed paperwork indicating that she had been exposed to COVID, *id*. at 73:25–74:7.

According to D.M.'s medical record from May 10, 2021, she saw a provider named Sunday Laird. GX 404, p. 7. The government did not call Ms. Laird to testify. Consequently, D.M.'s medical record from May 10, 2021—which Ms. Laird completed and signed that same day—was the only evidence of the medical decision making that occurred during the visit. The record indicates (1) that D.M.'s presenting problem was COVID exposure; (2) that she received two COVID tests, one rapid and one PCR; and (3) that the results of D.M.'s rapid test were reviewed on the same day as her visit. GX 404, pp. 7–8. D.M.'s limited recollection of her May 10, 2021 visit was not inconsistent on these points. Accordingly, based on the applicable coding guidance, she too had an undiagnosed new problem with uncertain prognosis. At the very minimum, there was simply not enough evidence from which the jury could conclude beyond a reasonable doubt that level 4 was the wrong code for this visit.

iv. Count 2: W.R., date of service 4/23/21

The government did not call W.R. to testify at trial. Instead, his daughter S.T. testified as to *her* memory of her father's visit at DEC. S.T. testified that W.R. sought a COVID test because he was exposed to S.T.'s COVID-positive daughter. 7/24/23 Tr. 107:15–24. S.T. testified that W.R. saw a provider via telehealth at Earleigh Heights, that W.R. had a conversation with that

provider, and that the conversation was brief. *Id*. at 108:1–25. S.T. remembered little else about her father's visit. *Id*. at 109:5–7.

W.R.'s medical record indicates that he was seen by Kathleen Wrona, a physician assistant whom the government did call to testify. *See* GX 407, p. 6. Ms. Wrona did not testify about the decisions she made during W.R.'s visit specifically, *see* 7/25/23 Tr. 203:17–206:6; 7/26/23 Tr. 49:12–54:10, although she did testify about the types of decisions she made during COVID test-related visits generally, *see* 7/26/23 Tr. 17:25–19:12, 23:12–18. Although W.R.'s medical record—which indicated an in-person physical exam—differed from S.T.'s recollection that her father had a telehealth visit, the existence or extent of a physical exam was irrelevant to code selection in 2021. W.R.'s record indicates that he presented with exposure to COVID and received two tests; on these points, the record is not inconsistent with S.T.'s testimony. Accordingly, based on the applicable coding guidance, there was simply not enough evidence from which the jury could conclude beyond a reasonable doubt that level 4 was the wrong code for W.R.'s visit.

In closing argument, the government pointed out that these four patients had brief encounters (though the visits varied in duration, and the patients' recollections were generally limited); that some were asymptomatic; and that their physical examinations were insufficient. *See* 8/3/23 Tr. 24:6–11, 24:19–25:4, 27:2–7, 30:6–12. These arguments reflect the fundamental fallacy in the government's evidence and its prosecution theory. Both Mr. Miscoe and Mr. Quindoza agreed that in 2021, if the level was based on medical decision making, the duration of the visit was simply not relevant to code selection, nor was the extent of the examination—if any.

The 2021 CPT Manual makes both points abundantly clear. The level of medical decision making was dictated by the medical decision making table. There is no question that for all four patients, the amount of data to be reviewed and analyzed—the middle column in the chart—was

moderate, because two tests were ordered and one was reviewed. It is also undisputed that all four patients were seen by a provider who performed some level of medical decision making. The only relevant factor that remains is whether these patients—exposed to a disease that killed more than 1 million people in the United States alone and, in one case, symptomatic—had an "undiagnosed new problem with an uncertain prognosis." The only expert testimony on that point was Mr. Miscoe's, and he testified that under the governing coding rules and guidance, these patients did in fact have an undiagnosed new problem with an uncertain prognosis. *See* 7/31/23 Tr. 173:23–175:6 ("[T]he instructions were that regardless of the reason the patient was being tested, there was a presumption that they had contact with or exposure . . . for that reason, it becomes classified as an undiagnosed new problem. And due to the nature of COVID, it's certainly a problem with an uncertain prognosis.").

The government's arguments concerning these four counts lay bare the lawless approach employed in this case. The government asked the jury to interpret "moderate level of medical decision making" based on their understanding of those words—not based on the rules in the CPT Manual. *See* 8/3/23 Tr. 92:18–20 ("[L]adies and gentlemen, you don't need to be a Certified Professional Coder to figure this out. Common sense says that the defendant's justification cannot be true."). Counsel went so far as to argue that the applicable code was level 1, because it was "symptom and exposure assessment and sample collection at mass testing sites." 8/3/23 Tr. 90:10–16. This contention illustrates what happens when complex binding rules are cast aside in favor of counsel's view of what the rules should be. In its May 8, 2020 Interim Final Rule, CMS made clear that level 1 applied only when the patient does not interact with a provider at all, and clinical staff—such as a medical assistant—does nothing more than use a swab to acquire a specimen for testing. DX 219, p. 56 ("CPT code 99211 typically does not involve interaction with physician or

other qualified health care professional and the usual presenting problem(s) are minimal. Thus, this CPT code typically is reported by a physician or practitioner when the patient only sees clinical office staff for services like acquiring a routine specimen sample.").

The evidence is undisputed that the patient encounters at DEC involved more than clinical staff taking a swab. All of the providers who testified at trial described encounters in which they reviewed patients' histories; examined them visually in the case of telehealth visits and physically if in person; determined whether to order additional or different tests than called for by the standing order; and advised the patients concerning CDC guidelines for quarantining, symptoms that should concern them, and whether to follow up with their primary care physicians or go to the emergency room. *See, e.g.*, 7/24/23 Tr. 137:10–14, 190:21–191:11; 7/26/23 Tr. 22:23–24:25; 7/31/23 Tr. 39:1–7; 8/1/23 Tr. 97:13–98:4, 100:8–101:20.

The government's case amounted to a bait and switch. CMS urged providers to see patients by telemedicine to reduce exposure risk and to see patients at the time they were tested. *See* DX 218, p. 5, 53; DX 233. CMS mandated that neither examination nor history would be factors in level selection. DX 218, p. 41. Yet the government contended throughout the trial that the patient visits were too brief and the examinations too limited for a level 4 visit. And the government contended that although providers did exactly what CMS urged them to do, the providers' encounters should be disregarded and the visits should be coded at level 1, as if nothing more happened than a medical assistant acquiring a swab.

CMS recognized that the pandemic called for extraordinary measures, and it changed coding rules to ensure that providers were financially incentivized to provide the care that was so important in the midst of the pandemic. *See* DX 218, p. 1.[16] Dr. Elfenbein responded. He is entitled

[16] As the Court acknowledged:

to have his coding determinations judged based on the governing rules published in the CPT Manual and modified by CMS. With the pandemic behind us, it is all too easy to rewrite the rules. But Dr. Elfenbein did not have notice of the rules that government lawyers would later invent; his conduct must be judged by the rules that existed at the time.

The same is true of diagnosis codes. CMS publishes the ICD-10 diagnosis codes, and it requires both diagnosis and CPT codes on every claim. On that point the experts agreed. Mr. Quindoza testified that every claim was required to include diagnosis as well as procedure codes, and the diagnosis codes were important to CMS. 7/18/23 Tr. 106:25–107:14. To the government's chagrin, Mr. Miscoe testified that the two types of codes work hand in hand, and that CMS's guidance was to treat all patients tested for COVID as suspected of exposure to COVID. 7/31/23 Tr. 175:11–21; *see also* DX 221, pp. 6–7. The government offered no evidence that CMS did not give the guidance to which Mr. Miscoe testified, and no witness testified that there was no such guidance, or that it meant something else.

> [I[f you're operating in an environment where the Government has basically on an emergency basis, because there's a pandemic, knocked out a lot of the rules, and even done it on a retroactive basis, it leaves the Government, it leaves you, it seems to me, in a very precarious position. I mean, ultimately, it's a system of laws, not expectations of moral, honest conduct.
>
> And it strikes me that at least on the surface that the Government made a decision which I'm not necessarily in disagreement with. We were in a national emergency here, huge crisis. We've got a highly regulated system by which we deliver health care in the country. That, you know, we're going to be like Gulliver here, tied down by all of the Lilliputian rules so we can't -- we can't be nimble, we can't move, we can't flex, we can't react. And then somebody had the wisdom in the Government to say, you know, the barn's on fire, let all the horses out; otherwise, they're all going to die.

7/19/23 Tr. 28:5–21.

This testimony was devastating to the government, because if every patient tested for COVID was diagnosed as possibly exposed to COVID, then every patient tested had an undiagnosed problem of uncertain prognosis—unless their diagnosis was confirmed. So perhaps it is not surprising that government counsel ridiculed Mr. Miscoe's testimony on this point. *See, e.g.*, 8/3/23 Tr. 91:17–22. But whatever the government's view, and whatever the merit of CMS's guidance, Mr. Miscoe was not the source of it. CMS issued the guidance and reinforced it in its published update concerning ICD-10 codes related to COVID. In this respect as well, the government substituted its own view for binding guidance from CMS because it found the CMS guidance illogical, or at least unhelpful to its case. But the government was no more entitled to rewrite the binding CMS rules than was Dr. Elfenbein—and the jury certainly was not permitted to convict Dr. Elfenbein for following CMS guidance simply because that guidance might now appear unreasonable.

C. The jury had no reasonable basis to find that Count 1 constituted an execution of the alleged scheme because there was no scheme—alleged or otherwise—to bill for visits that did not occur.

Count 1 of the indictment alleges that the submission of a level 4 claim for an E/M service provided to A.H. on March 25, 2021 constituted an execution of the scheme. Sup. Ind. ¶ 31. Unlike every other patient who testified at trial, A.H. testified that she did not receive a provider visit at all. 7/19/23 Tr. 133:8–15. A.H.'s medical records, however, indicate that she had a visit with DEC provider Sunday Laird. GX 403, p. 7. The government did not call Ms. Laird to testify and presented the jury with no explanation as to why Ms. Laird would complete and sign a chart for

an office visit that did not occur. Nevertheless, assuming that A.H.'s recollection of her visit was accurate, and she did not see Ms. Laird,[17] level 4 would have been the wrong code.

The government, however, did not charge Dr. Elfenbein with a scheme to bill for visits that did not occur. The alleged scheme related to the level, not the existence, of the visit. There was not a shred of evidence that Dr. Elfenbein instructed providers to bill for visits that did not occur. The only evidence on this point was that Dr. Elfenbein took steps to ensure that there was no E/M claim if a patient was not seen by a provider. *See* DX 51 (instructing providers to ensure that records were not created until after the provider had made contact with the patient, because "[d]oing so beforehand generates too much a possibility of accidental fraudulent billing and too much work on the back end to delete all the encounters that are filed out.").[18] If Ms. Laird submitted a claim for a visit she did not perform, there is no evidence whatsoever that this submission would have been anything other than a mistake—and it was certainly not consistent with Dr. Elfenbein's instructions.

If A.H. was seen by a provider, the only evidence concerning the visit is the medical record. It reflects that she was 71, had diabetes, high blood pressure, and asthma, and that she reported a sore throat. GX403, pp. 7, 19; *see* 7/26/23 Tr. 12:7–13:23; 7/31/23 Tr. 87:6–25. She received a

[17] It is equally (if not more) likely that A.H.'s recollection of events was faulty. She was adamant that her vitals were not taken at Earleigh Heights, despite the fact that handwritten vital signs appear in her record. *See* 7/19/23 Tr. 130:9–131:18; GX 403, p. 23. A.H. was also confident in her recollection that when she called the phone number listed on her Explanation of Benefits, she spoke to someone at DEC and complained about the charge to Medicare. *Id*. at 119:12–120:21. The only phone number for DEC listed on A.H.'s Explanation of Benefits, however, was a fax number. *Compare* GX 414 *with* GX 401, p.1. But we assume that, taking the evidence in the light most favorable to the government, the jury could have found that A.H. did not see a provider.

[18] As discussed *infra*, the Court erroneously excluded an email that would have established that Dr. Elfenbein explicitly instructed providers *not* to bill a provider visit when only a swab was taken. *See* DX 60.

rapid test, for which the result was reviewed on the same day, and a PCR test. As with the other four counts, the evidence was not sufficient for the jury to find that the code for A.H.'s visit was incorrect except if she did not see the provider, in which case there is no evidence that her claim constituted an execution of the alleged scheme or was consistent with Dr. Elfenbein's instructions. The Court should enter a judgment of acquittal on all five counts.

II. IN THE ALTERNATIVE, THE COURT SHOULD GRANT A NEW TRIAL UNDER RULE 33.

Under Federal Rule of Criminal Procedure 33(a), the Court may order a new trial "if the interest of justice so requires." "The 'ultimate test' of whether a new trial is warranted is 'whether letting a guilty verdict stand would be a manifest injustice.'" *United States v. Rafiekian*, 68 F.4th 177, 190 (4th Cir. 2023) (quoting *United States v. Ferguson*, 246 F.3d 129, 134 (2d Cir. 2001)). Allowing the jury's verdict to stand would be a manifest injustice. At minimum, for the reasons explained below, the Court should grant a new trial.

A. The weight of the evidence does not support a finding of guilt.

"[A] new trial based on the weight of the evidence is warranted '[w]hen the evidence weighs so heavily against the verdict that it would be unjust to enter judgment.'" *United States v. Rafiekian*, 68 F.4th 177, 186 (4th Cir. 2023) (quoting *United States v. Arrington*, 757 F.2d 1484, 1485 (4th Cir. 1985)). In determining whether to order a new trial pursuant to Rule 33, the court "conducts its own assessment of the evidence, unconstrained by any requirement to construe the evidence in the government's favor." *Id.*

For all the reasons discussed above, the evidence was insufficient to convict. But even if the Court concludes otherwise when construing the evidence in the light most favorable to the government, a new trial is nevertheless warranted under Rule 33 because the evidence preponderates strongly against the verdict. Throughout the trial, the government urged the jury to

draw nefarious conclusions from evidence that was irrelevant to the determination whether CPT codes 99204 and 99214 were appropriate—the only basis for its allegation that false statements were made in furtherance of a scheme to defraud.

For example, arguing that Dr. Elfenbein knew that patients were only there to be tested adds nothing to the determination of the degree of medical decision making necessary for a particular code. This is especially true given that the only medical expert who testified, Dr. Hill, stated that providers needed to conduct some level of examination and assessment and not just administer a test. *See* 7/31/23 Tr. 74:25–75:24. And CMS reinstated its requirement of an order for every test after a patient's first one in order to ensure that patients saw providers when tested, E/M visits for which the providers were entitled to be paid even if they did nothing more than counsel patients. *See* DX 220, pp. 19–20.

Also, with respect to the level of decision-making that occurred, the government suggested repeatedly throughout the trial, and argued to the jury in closing argument, that little to no work or medical decision making was performed during the office visits occurring at DEC. 8/3/23 Tr. 20:8–13. These assertions ran contrary the testimony of *every DEC provider who testified at trial*, including the two providers called by the government. *See, e.g.*, 7/24/23 Tr. 138:11 (Deb Needle: "we were trying to see patients and save lives.").

Additionally, in closing argument, the government improperly urged the jury to disregard the complexities of the CPT coding guidance and instead rely on their "common sense" judgment about what "moderate complexity" *should* mean. *See* 8/3/23 Tr. 18–23. At the same time, the government essentially admitted that the correct code for COVID-related visits was unknowable:

> So you may be asking yourself, what question [*sic*] should have been billed in this cases, and *the good news for you is you don't have to figure that out*. You don't have to decide if it's a 3 or a 2 or a 1. The

> only thing you have to decide is . . . that these visits, including our five count beneficiaries, were not a level 4.

8/3/23 Tr. 28:6–9. It is inconceivable that a jury could be asked to decide that a false statement was made in furtherance of a scheme to defraud based on the level of E/M services in a claim for reimbursement when asked to simply intuit what would be correct, untethered from the controlling rules.

Perhaps the most common arguments made by the government throughout the trial were that the number of patients tested and seen by providers was too many for a meaningful E/M visit, and that the five minute duration of the average visit was too short for a level 4 visit. *See, e.g.*, 7/18/23 Tr. 20:20–21:8, 22:15, 23:12, 26:8–12; 7/20/23 Tr. 69:19–23; 7/24/23 Tr. 101:21–25, 103:19–21, 108:17–25. The government may believe that the duration of visits should be relevant to the level of medical decision making, or that a level 4 visit should be longer than five minutes. But the rules established by the CPT Editorial Panel have no minimum—and in 2021 (and 2020 for telehealth visits), not even a typical duration. The government—and the jury—simply are not free to disregard the coding rules in this respect any more than in any other respect. Of course, if no encounter occurred at all, there was no basis to bill an E/M visit (other than a level 1 visit if the clinical staff took a swab). But the indictment did not allege that there was no E/M visit, the providers did not testify that they billed visits that did not occur, and Dr. Elfenbein instructed providers to ensure that they did not even inadvertently bill visits that did not occur.[19]

[19] The government emphasized that on the busiest days during the worst surges, providers saw more than 150 patients in a day. According to the providers and the medical assistant in charge of Earleigh Heights, providers worked 12-hour shifts that could stretch to 14 hours. *See* 7/31/23 Tr. 16:13–20, 53:2–9, 53:21–25. Dr. Hill testified that he has treated patients in 20 seconds, but agreed that he wouldn't want to. 7/31/23 Tr. 114:25–115:4. He testified that he could not do an entire physical exam and history in one minute, *id.* 115:5–6, but the E/M level was not based on and did not require a history or physical, except for in-person visits in 2020.

The irony in this case is that the government, which ordinarily seeks strict enforcement of rules, wants nothing to do with them here. The government never attempted to apply the CPT rules and CMS binding rules and guidance concerning their application during the pandemic. Indeed, at the outset of the case, the government believed that time was a factor in code selection in 2020 and 2021; that the rules for telemedicine code selection were never changed during the pandemic; that the examination was a factor in code selection for telemedicine, even in 2021; and that selecting the applicable code was as simple as construing words like "moderate" and straightforward." By the end of the trial, each of these misunderstandings of the rules had been conclusively refuted—but the government continued to argue that the jury should disregard the rules and decide the case based on their own assessment of "moderate complexity." Dr. Elfenbein was convicted of health care fraud based on standards devised by government lawyers in 2023, without regard to the rules in place during 2020 through 2022. Even if the Court believes that the evidence was sufficient to permit the jury to find Dr. Elfenbein guilty, it would be "unjust to enter judgment" based on a government theory of prosecution that was untethered from the controlling code selection rules. At a minimum, the Court should grant Dr. Elfenbein a new trial.

B. The Court's exclusion of key non-hearsay evidence offered by the defense and admission of highly prejudicial hearsay testimony offered by the government warrants a new trial.

i. The Court improperly excluded contemporaneous evidence of Dr. Elfenbein's state of mind that went to the heart of his defense.

At trial, the defense offered a number of emails as contemporaneous evidence of Dr. Elfenbein's state of mind. "[E]mail [is] a medium of communication that seems particularly prone to candid, perhaps too-candid, statements of the declarant's state of mind, feelings, emotions, and motives." *Lorraine v. Markel Am. Ins. Co.*, 241 F.R.D. 534, 570 (D. Md. 2007) (Grimm, M. J.). Accordingly, even where emails contain hearsay statements, a hearsay exception may permit their

admission. One exception to the hearsay rule in Federal Rule of Evidence 803(3) "permits the statement of the declarant's state of mind, sensation, mental, emotional, or physical condition, as well as statements of motive, intent, plan or design," and may be "used to prove a wide variety of matters," including "motive [and] lack of intent to defraud." *Id*. Moreover, statements in emails not offered for their truth, but instead as evidence of the declarant's state of mind, are not hearsay in the first instance. *See United States v. Martin*, 657 F. App'x 193, 199–200 (4th Cir. 2016) (citing cases). The emails offered by the defense were admissible for both reasons.

The government relied heavily on Dr. Elfenbein's emails during its case-in-chief. In opening statement, the government asserted repeatedly that "the defendant's own words" would establish that he "lie[d] for money" and was "[m]otivated by greed." *See* 7/18/23 Tr. 20:8–10; *id*. at 21:14–15; *id*. at 22:13–14. The government explicitly contended that Dr. Elfenbein's emails were evidence of his state of mind: "you'll see e-mails in the defendant's own words. *Pay close attention to these e-mails*. The e-mails will show that Defendant Elfenbein . . . knew that these so-called visits were simple and straightforward . . . *because that is what he wrote*." *Id*. at 26:8–16 (emphasis added). Consistent with this position, the government introduced numerous emails from Dr. Elfenbein throughout its case to show his state of mind. During the defense case, however, the government objected on hearsay and relevance grounds to admission of Dr. Elfenbein's emails, even when they were evidence of his state of mind.

The Court excluded three emails the defense sought to introduce: DX 77, DX 60, and DX 66. All three were erroneously excluded.

DX 77:

The defense offered a December 18, 2021 email from Dr. Elfenbein to providers thanking them "for all [their] hard work under extraordinary and incredibly difficult circumstances." Dr.

Elfenbein wrote, "I know volumes are overwhelming, but please understand the WHY. The why is all those people we are helping. . . . **I COULD NOT BE PROUDER...**" DX 77 (emphasis in original). He further explained, "An individual we helped. An individual who is scared, has no place else to go and might be ill. WE helped that person. Be it thru a test (which in and of itself can help in so many ways), thru a lifesaving infusion, thru a 'regular urgent care visit,' a vaccination, or anything else we do, WE were the solution to their problem. We allowed them to travel, visit grandparents, volunteer, spend the holidays with family, reduced their risk of dying/hospitalization, go back to work, go back to school, play sports, put on a play, etc...."

The defense did not offer DX 77 for the truth of any matters asserted therein. 8/1/23 Tr. 163:13–18. The point was not that the testing and related services provided at DEC had in fact reduced the risk of dying or hospitalization; it was that Dr. Elfenbein's motive was to help patients, not to make money. The email was introduced to rebut the government's contention that Dr. Elfenbein was "[m]otivated by greed." *See* 7/18/23 Tr. 20:8–10. The exclusion of an email that is direct evidence of motive contrasts with the admission of the government's summary exhibit that showed the jury Dr. Elfenbein's income from his tax returns, which the court found "minimally probative of his motive and intent." ECF No. 44, p. 2.; DX 77. *See United States v. Safavian*, 435 F. Supp. 2d 36, 45 (D.D.C. 2006) (ruling admissible emails that "might help to explain [the defendant's] motive and intent at the time he undertook certain actions").

Nor was the Court's proposed alternative to the admission of DX 77 sufficient. In excluding DX 77, the Court stated:

> Seems to me the proper way to examine this witness is to simply ask him questions about what efforts he was making -- . . . That he was working hard to keep his head above water and that circumstances were demanding, taxing, at times overwhelming, and all of that necessitated frequent coaching and encouragement and cheerleading with the staff to keep the enterprise afloat and to keep

> the medical service and care flowing to the community. All of that can be explained by the witness who is right here, live, and in person.

8/1/23 Tr. 163:19–164:7. Dr. Elfenbein's testimony at trial does not negate the relevance and admissibility of an email that would have served as crucial corroboration of Dr. Elfenbein's testimony about his state of mind at the time. *See United States v. Ibisevic*, 675 F.3d 342, 351 (4th Cir. 2012) (finding reversible error where "the excluded testimony was the only evidence that would have corroborated the defendant's own testimony of assertedly innocent conduct"); *Martin*, 657 F. App'x at 201 (reversing conviction where testimony of the defendant was "not an adequate substitute for the evidence that would have been heard by the jury had the [out-of-court statements offered for a non-hearsay purpose] not been improperly excluded").

The importance of such evidence is reinforced by the Court's instruction to the jury that state of mind may be inferred "from what one says or does: one's words, one's actions, and one's conduct, as of the time of the occurrence of certain events. The intent with which an act is done is often more clearly and conclusively shown by the act itself or by a series of acts, than by words or explanations of the act uttered long after its occurrence." 8/3/23 Tr. 123:24–124:5. Admitting contemporaneous emails that the government contended showed greed, but excluding other contemporaneous emails offered by the defense that showed that Dr. Elfenbein's motive was to help people, left him in the impossible position of testifying to his motive without the ability to offer his contemporaneous statements of his motive, which the Court instructed the jury were much more important. Accordingly, exclusion of DX 77 was error.

DX 60:

The defense offered a February 11, 2021 email exchange between Dr. Elfenbein and several employees.[20] In Dr. Elfenbein's first message in the thread, he asked questions and provided instructions:

- I see on Sweeny no results in chart…Laquelle, why no results? Can we get the results loaded in like theyre supposed to be?"
- If you look at Davis...It clearly states "Pt here for re-swab of PCR only."
- It should be a nurse visit. Rhonda, can you fix that?

Laquelle responded that Mrs. Sweeney "ended up leaving the [testing] line for unknown reasons. Only her evist appointment was canceled not her encounter, I apologize. It is canceled now." Regarding Mrs. Davis, Laquelle responded that "On the 28th she came back to get re-swabbed for her PCR test only."

In Dr. Elfenbein's second message, he repeated and expanded on his earlier instructions:

- "Andre, delete that encounter please. Please keep a log of who you see to avoid things like this. Had you accidentally billed that chart it would be fraudulent billing. Please know who you see-maintain a list of chart in real time."
- "Laquelle, please be sure they are deleting people who leave."
- "Yes…Davis..like I said should be a nursing visit. Can you fix that Rhonda? It SHOULD NOT be billed……. as of now there is a[n] EM code of 99204… THAT CANNOT be billed like that."

[20] The government objected only to emails *from* Dr. Elfenbein in this exchange, not emails *to* him. *See* 8/2/23 Tr. 28:25–29:4) ("MR. PHELPS: And Your Honor, if it's any assistance, we'll limit objections to hearsay statements by Dr. Elfenbein himself. THE COURT: Okay. Great. So I can skip over the rest. The rest are all admissible.")

The government objected to this email on the grounds that it was "irrelevant character evidence." 8/2/23 Tr. 34:6–8. The Court agreed, and prohibited the defense from responding in full:

> THE COURT: I get it. Mr. Bernstein, it does look like another example of the defendant taking the opportunity to pull up exhibits that show, "Look, generally, I complied with the law. It's not exactly in that COVID E/M coding context, but I give instructions to people and I tell them, follow the law, don't break the law." Why isn't this just like the one we had before?
>
> MR. BERNSTEIN: Well, only to the extent that he's referencing the 99204 code, which –
>
> THE COURT: No. Excluded. All right. Now, 65.

Id. at 34:16–25.

The Court's ruling that DX 60 was irrelevant was plainly error. The government's central allegation against Dr. Elfenbein was that he instructed his providers to bill encounters related to COVID-19 testing at CPT levels he knew were unsupported. DX 60 is evidence that directly undercuts that theory. The email demonstrates that when Dr. Elfenbein became aware of a COVID-19 encounter for a patient who came to DEC to be re-swabbed *for a PCR test*, which was improperly coded at 99204, he instructed his staff to change it—and to take steps to avoid such errors in the future. The email directly rebuts the government's arguments that every time a patient was tested, Dr. Elfenbein instructed providers and staff to code the visit at level 4.

Moreover, the email rebuts the government's argument that Dr. Elfenbein knew that all or most visits should be coded at level 1, because services were "provided by clinical staff to assess symptoms and take specimens for COVID-19 laboratory testing for all patients." DX 219, p. 56 (May 8, 2020 CMS Interim Final Rule). In this case, the patient had already been swabbed for a PCR test, and apparently because of a problem with the swab, needed to come back to be re-

swabbed again for a PCR test. Had Dr. Elfenbein not instructed his staff to change the code, it would have been a level 4 office visit on the same day as a test, and therefore part of the alleged scheme. But Dr. Elfenbein recognized that it should not be coded as an E/M visit at all, but only a nurse visit. Especially given that the code discussed in the email was 99204, DX 60 was clearly relevant.

Similarly, the other problem addressed in the email is a chart in which there were no test results. When Dr. Elfenbein asked questions, he learned that the patient had left the testing line, but her encounter had not been deleted. Although the code is not specified, had Dr. Elfenbein not intervened, it would have been erroneously billed as an encounter with a test—presumably a level 4 visit—and would have been part of the alleged scheme. Dr. Elfenbein instructed the provider to delete the encounter, and to take steps to ensure that the error was not repeated by maintaining a log of patients seen so that only their encounters were billed.

The central theme of the government's case was that Dr. Elfenbein's goal was to bill as many as possible level 4 codes for office visits associated with tests. In the government's closing argument, counsel argued, "He wants to churn through the patients. That's what he wanted." 8/3/2023 Tr. 33:8–9. The government contended that Dr. Elfenbein did not reduce to level 3 visits where only a rapid test was conducted, which was evidence of intent to defraud. *Id.* at 33:10–34:2. Government counsel argued that whenever a patient showed up for a test, Dr. Elfenbein wanted to bill a level 4 visit. But DX60 shows that when a patient was re-swabbed for a PCR test and therefore did not need to see a provider, he was emphatic that no E/M code be billed. And when a patient left the line and was not tested, he was emphatic that no claim should be billed. Instructing staff and providers not to bill E/M codes that, if billed, would be part of the alleged scheme is clear evidence of lack of intent to defraud. The Court was mistaken in reading the email as ***"not exactly***

in that COVID E/M coding context, but I give instructions to people and I tell them, follow the law, don't break the law." 8/2/23 Tr. 34:6–8 (emphasis added). DX 60 was precisely in the COVID E/M coding context.

Moreover, DX 60 contained no hearsay statements, only questions and instructions. "[S]tatements that are questions or imperative commands" are not hearsay "because they are not offered to prove the truth of the assertions." *Lorraine v. Markel Am. Ins. Co.*, 241 F.R.D. 534, 566–66 (D. Md. 2007). To the extent Dr. Elfenbein's questions and instructions were followed or preceded by statements that could otherwise be classified as hearsay, they were nonetheless admissible to establish context. *Cf. United States v. Leake*, 642 F.2d 715, 720 n.6 (4th Cir. 1981) ("Leake's testimony regarding his conversation with Graham would be meaningless unless both sides of the conversation were recounted to the jury. Graham's statements to Leake were admissible, therefore, as necessary to explain the context in which Leake made the statements revealing his state of mind."). Even if DX 60 contained hearsay statements (it does not), it would still be admissible under Rule 803(3). *Lorraine*, 241 F.R.D. at 570 (statements demonstrating a "lack of intent to defraud" may be admissible as state-of-mind evidence).

DX 66:

Finally, the defense offered a March 13, 2021 email from Dr. Elfenbein to Jimmy Brothers. Like DX 60, it was largely an instructional email:

- "Saw you made some changes to the billing and such in the template. PLEASE DO NOT do that without speaking to me first."
- "Cannot bill E&M level 5 AND critical care and this doesn't meet critical care designation. We also cannot bill for IV hydration as we are not hydrating, we are infusing."
- "Please fix the coding on his chart to reflect above- remove billing or the medicine/remove critical care and remove the IV

> hydration. Then resubmit and let Kim Turner know NOT to bill the first stuff you sent on him."

The Court excluded DX 66 because of its "character quality." 8/2/23 Tr. 37:15–16. As explained above, however, Dr. Elfenbein's instructions on proper coding levels, and his reactions to the assignment of codes that do not reflect visits actually performed, are clearly relevant as to his then state of mind and intent. Moreover, instructions are not hearsay, and even if DX 66 did contain hearsay, it should have been admissible under Rule 803(3). Nor is it sufficient for the government to argue that coding of infusions of monoclonal antibodies was not at issue. First, the instruction rebutted the government's contention that providers were instructed not to change codes in templates to ensure that codes were not reduced to lower levels. It reflects that Dr. Elfenbein's concern about changing codes was not loss of revenue, but the use of codes incorrectly—in this case, the use of a level 5 code only if it was supported. Second, the use of level 5 codes was part of the alleged scheme, and evidence that Dr. Elfenbein tried to ensure that those codes were used correctly in COVID-19 care was central to the defense. This was not mere evidence that Dr. Elfenbein complied with the law in other respects; it was evidence that he tried to use the E/M codes at issue correctly.

The Court's narrow view of permissible evidence of good faith and lack of motive and fraudulent intent kept from the jury essential evidence of Dr. Elfenbein's attempts to use E/M level 4 and 5 codes only when he believed they were supported, and that he was motivated by his desire to provide essential treatment to patients. The case turned on two issues: Dr. Elfenbein's intent, and the codes billed for E/M visits. Given the absence of any evidence that the concerns of the handful of employees who claimed to have been uncomfortable with level 4 E/M codes were justified, and the codes were incorrect, the jury may well have been persuaded by the picture painted by the government of Dr. Elfenbein as motivated only by money. The emails showing that

he stopped unjustifiable billing of level 4 and 5 E/M codes, including codes related to COVID testing, and that his motive was to help patients, were essential to rebut the government's allegations. Their exclusion was error.

ii. The Court erroneously allowed A.H. to testify to the hearsay statement of an unknown individual who purportedly said, "this is how we bill."

During the testimony of A.H., the government elicited testimony regarding a conversation she purportedly had with an employee of DEC. Specifically, A.H. testified that after she received her Medicare Explanation of Benefits ("EOB"), she called the number listed for Drs ERgent Care on the EOB to complain about the charge to Medicare for a service she claims she didn't receive. 7/19/23 Tr. 115:14–22. Over defense objection, the Court permitted A.H. to testify that the person she spoke with on the phone told her, "this is how we bill," when A.H. told them she did not see a provider. *Id*. at 119:11–120:21.

Where a party seeks to introduce a hearsay statement pursuant to the "agency" exception contained in Federal Rule of Evidence 801(d)(2)(D), the "proponent of the evidence has the burden to demonstrate that an individual qualifies as an 'agent.'" *Contracts Materials Processing, Inc. v. Kataleuna GmbH Catalysts*, 164 F. Supp. 2d 520, 530 (D. Md. 2001); *see Rhodes v. Wells Fargo Bank, N.A.*, Civil Action No. 3:10-cv-02347-L, 2013 WL 2090307 at *6 (N.D. Tex. May 14, 2013) (finding that plaintiffs did not meet their burden of showing that "unidentified persons or persons referred to only by first name in Rhodes's affidavit were agents or employees of Wells Fargo or that the statements were made by agents or employees of Wells Fargo in the scope of their employment or agency").

Here the government did not meet its burden of showing that the unknown person on the other end of the phone was an agent of Dr. Elfenbein. A.H. testified that the person who answered gave a first name that A.H. did not remember, did not identify his or her position or mention the

name of the company, and did not confirm that A.H. was one of their patients. *See* 7/19/23 Tr. 119:14–120:13. She testified that the only reason she thought she was talking to somebody about the bill she was disputing was because the phone number she called was on the Medicare explanation of benefits. *Id.* at 120:10–13.

The Court should not have allowed A.H.'s testimony regarding the alleged phone call. The supposed "admission" from the person on the other end—that, as a matter of course, DEC bills for visits that did not happen—was both inflammatory and unsupported by the evidence. Before finding that the government had met its burden to demonstrate that the person A.H. testified she spoke to was an agent of Dr. Elfenbein, the Court should have required something more than A.H.'s vague testimony. The only basis for her belief that she was talking to someone at DEC was that the number she called was on the explanation of benefits—but the explanation of benefits also listed a post office box in Belfast, Maine. GX 414, p. 3. Moreover, the phone call may not have happened at all. The only phone number for Drs ERgent Care listed on A.H.'s EOB was a fax number. *Compare* GX 414 *with* GX 401, p.1.

The Court permitted her testimony based on its finding that the business, "for purposes of this proceeding and based on the evidence presented so far is effectively an alter ego of the defendant." 7/19/23 Tr. 122:9–15. But A.H. was the second witness at trial; only Mr. Quindoza testified before her. There was no basis to find that Dr. Elfenbein and Drs ERgent Care were alter egos. Moreover, subsequent testimony established that by the time Ms. Raymond left in October 2020—well before A.H.'s visit—the central billing office at Centennial Medical Group, headed by Erin Sharp who did not report to Dr. Elfenbein was responsible for billing. 7/24/23 Tr. 58:11–59:4. There was no reason to believe that calls concerning billing—assuming that A.H. reached a

person rather than a fax line—were handled by anyone at DEC rather than someone at the central billing office.

The prejudice from this testimony was especially substantial because it had no relevance—the scheme alleged in the indictment did not include billing for encounters that did not occur. It also ascribed to Dr. Elfenbein an intent to bill for encounters that did not occur based on a conversation with an unidentified person who may not even have worked for DEC. The admission of this highly prejudicial testimony exacerbated the harm caused by the exclusion of three key emails that negated the government's evidence of Dr. Elfenbein's intent and motive. A.H.'s testimony should have been excluded, and the Court's failure to do so, taken together with its exclusion of three critical emails that were contemporaneous evidence of Dr. Elfenbein's state of mind, warrants a new trial.

C. The Court should not have closed *voir dire* to the public.

Criminal defendants have a Sixth Amendment right to a public trial. *Presley v. Georgia*, 558 U.S. 209, 212 (2010). "[A] violation of the right to a public trial is a structural error," *Weaver v. Massachusetts*, 582 U.S. 286, 296 (2017), and such errors may "require reversal because they cause fundamental unfairness," *id.* at 301. The Court closed the trial to the public during jury selection. Because the infringement of Dr. Elfenbein's right to a public trial "affect[ed] the framework within which the trial proceeds," *id*. at 925 (quoting *Arizona v. Fulminante*, 499 U.S. 279, 306, 309 (1991)), he is entitled to a new trial.

At the beginning of the individual questioning of jurors, the Court ordered members of the public who were not direct participants in the trial to leave the courtroom. 7/17/23 Tr. 31:16–23. Defense counsel stated that Dr. Elfenbein's wife wished to stay in the courtroom. *Id*. at 32:9–10. The Court responded as follows:

> **MR. BERNSTEIN:** Dr. Elfenbein advises that his wife really wants to be here.
>
> **THE COURT:** All right. Well, if she's going to be here, then we have to permit anybody to be here. So then by agreement of counsel with the approval of the Court, because the Government says they don't object. We have got one problem, though. We've instructed the jurors, we've instructed the jurors that the normal practice would be followed. I'm not sure how I'm going to undo that.
>
> **MR. BERNSTEIN:** Your Honor --
>
> **THE COURT:** I'm going to stick with the practice. So any -- no one can be in the courtroom during the individual *voir dire* unless they are a direct participant in the trial, so let's identify the persons who wish to remain in the courtroom or who are not departing. I see people picking up their things and departing so it looks like we are not going to be identifying anybody.

Id. at 32:11–25. After the Court stated that it would follow this practice, government and defense counsel agreed that it was acceptable. *Id*. at 33:5–9.

While "there are exceptions to th[e] general rule" that voir dire must be open to the public, *Presley*, 558 U.S. at 213, exceptions are "rare," and "trial courts are required to consider alternatives to closure even when they are not offered by the parties." *Id*. at 213–14. Because the Court did not consider alternatives before closing the courtroom and simply chose to follow "its normal practice," Dr. Elfenbein is entitled to a new trial. The acquiescence by defense counsel, after the Court had stated how it would proceed, does not cure this structural error.

CONCLUSION

For the reasons explained above, the Court should grant judgment of acquittal on all counts or, at a minimum, grant a new trial.

August 18, 2023
Baltimore, MD

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on this 18th day of August 2023, a copy of the foregoing Defendant Ron Elfenbein's Motion for Judgment of Acquittal or, in the Alternative, for a New Trial, was served via CM-ECF to:

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